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| 09/840,085      | 04/24/2001  | Alanna Schepartz Shrader | 044574-5099-US      | 2186             |

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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

13

DATE MAILED: 01/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/840,085

Applicant(s)

SHRADER ET AL.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 November 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION***APPLICANTS' ELECTION*

Applicants' election without traverse of Group I (claims 1-13 and 19; drawn to polypeptides) and SEQ ID NO: 23 in Paper No. 9, filed 08 October 2002, is acknowledged. The species election requirement (Species A: basic region leucine zipper structures; Species B: basic helix loop helix structures) as set forth in Paper No. 8, mailed 02 July 2002, is vacated on the grounds that applicants' traversal argument is found persuasive wherein the above species are not patentably distinct. Applicants' traversal argument that the "search of any one of the amino acid sequences of SEQ ID NOs: 23-30 ... would necessarily reveal art regarding the other sequences" and "request withdrawal of the election of the species requirement requiring election of a single amino acid sequence and request that the sequences relating to Bcl-2, e.g. SEQ ID NO: 23-30, be examined" is found unpersuasive. Applicants are directed to the restriction/election requirement set forth in Paper No. 8, mailed 02 July 2002, wherein **"Each sequence is patentably distinct because they are unrelated sequences... It is noted that this is a restriction requirement to a single sequence and NOT a species election requirement... different proteins are structurally distinct chemical compounds and are unrelated to one another..."**. Additionally, claims 1-13 are withdrawn on the grounds that the specification provides a definition of an avian pancreatic polypeptide (instant claim 1, line 1) wherein an "Avian pancreatic polypeptide (aPP) is a polypeptide in which residues fourteen through thirty-two form an alpha helix stabilized by hydrophobic contacts with an N-terminal type II polyproline (PPII) helix formed by residues one through eight" (page 3, lines 7-10 of the Specification). The elected SEQ ID NO: 23 (15 amino acids) fails to fulfill at least the defined

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requirement of an avian pancreatic polypeptide. In fact, the specification indicates that the elected SEQ ID NO: 23 is a protein-binding miniature protein (page 15, lines 10-12 of the Specification). Thus, claims 1-18, 20-22, and all sequences other than SEQ ID NO: 23 are withdrawn from examination as not directed to the elected invention.

*CLAIM UNDER EXAMINATION*

The claim herein under examination is claim 19 and SEQ ID NO: 23.

*TITLE NOT DESCRIPTIVE*

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to DNA and protein binding miniature proteins whereas in contrast the elected claims are directed to an avian pancreatic polypeptide also include constructs and recombinant host cells, but not polypeptides.

*PATENTABLE UTILITY*

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

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"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

### **Rejection of Claims Under 35 U.S.C. § 101**

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

#### *LACK OF PATENTABLE UTILITY*

Claim 19 is rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either a specific, substantial utility, and credible asserted utility or a well established utility.

The sequence listing identifies SEQ ID NO: 23 as a 15 amino acid residue polypeptide sequence. The specification indicates that the SEQ ID NO: 23 is a protein-binding miniature protein isolated from the phage display library capable of binding to Bcl (page 15, lines 10-12 of the Specification). No additional information is provided.

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The claimed polypeptides are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any polypeptide. The specification states that the "binding of miniature proteins modulates protein-protein and/or protein-ligand interactions. Thus, in some embodiments the binding blocks the association (or specific binding) of ligands and receptors" (page 13-14, lines 32 and 1-2, respectively). These are non-specific uses that are applicable to polypeptides in general and not particular or specific to the polypeptide being claimed. In fact, the specification summarized modern biotechnology generally but never connects any of the specifically elected sequences to any particular or specific utility. This wishlist desire for a utility for the claimed sequences falls short of a readily available utility.

Further, the claimed polypeptides are not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein/polypeptide. The protein/polypeptide could then be used in conducting research to functionally characterize the protein/polypeptide. The need for such research clearly indicates that the protein/polypeptide and/or its function is not disclosed as to a currently available or substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, none of the proteins/polypeptides produced as final products resulting from processes have asserted or identified specific and substantial utilities. The research contemplated by applicant(s) to characterize potential protein products, especially their biological activities, does not constitute a specific and substantial utility. Identifying and studying the properties of a protein itself or the

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mechanisms in which the protein is involved does not define a "real world" context or use.

Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide compound(s) such that another non-asserted utility would be well established for the compounds.

### **Rejection of Claims Under 35 U.S.C. § 112 1<sup>st</sup> Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

#### *LACK OF ENABLEMENT*

Claim 19 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, since the claimed invention is not supported by a specific or substantial utility, or, alternatively, a well established utility for the reasons set forth above (Refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention.

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**Claims Rejected Under 35 U.S.C. § 112 2<sup>nd</sup> Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*VAGUE AND INDEFINITE*

Claim 19 is vague and indefinite for failing to reflect the elected SEQ ID NO: 23 (i.e. instant claim 19, line 1; "an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 8, 9, 10, ..."). The above claims have been examined as though the claims recite SEQ ID NO: 23 alone.

**Claims Rejected Under 35 U.S.C. § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 19 is rejected under 35 U.S.C. § 102(a) and (b) as being anticipated by the Genbank sequences listed below for the instantly elected SEQ ID NO: 23. The Genbank Accession No. P38803 sequence is a fragment of at least twelve (12) amino acids, has one or more conservative amino acid substitutions, and has one or more naturally occurring amino acid sequence substitutions. The Genbank Accession No. P43316 sequence is an isolated polypeptide



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comprising one or more conservative amino acid substitutions and comprises one or more naturally occurring amino acid substitutions. The 102(a) versus 102(b) type of Genbank sequence is determined by the publication date for each sequence where 102(a) sequences were published as prior art on or after 24 April 2000 102 (b) prior art sequences were published before 24 April 2000.

| SEQ ID NO: | Genbank Accession No. | 102 Sec. | % Identity |
|------------|-----------------------|----------|------------|
| 23         | P38803                | 102(a)   | 55.7%      |
| 23         | P43316                | 102(b)   | 57.1%      |

*PRIORITY NOT GRANTED*

Priority to Provisional U.S. Application Nos. 60/199,408; 60/240,566; 60/265,099; and 60/271,368 are not granted. Absent in the said Provisional U.S. Applications is a sequence compliant computer readable form to which the elected SEQ ID NO: 23 can be searched. Further, absent is a statement indicating the polypeptide sequence (page and line number) in Provisional U.S. Application Nos. 60/199,408; 60/240,566; 60/265,099; and 60/271,368 for which SEQ ID NO: 23 corresponds to.

*OBJECTION TO DISCLOSURE*

The disclosure is objected to because of the following informalities:

Page 1 (lines 8-12) of the specification states the following: "This application claims the benefit of U.S. Provisional Applications 60/199,408 filed April 24, 2000; 60/240,566 filed October 13, 2000; and U.S. Provisional Applications entitled "Small Polypeptide Molecules that Bind DNA or Proteins with High Affinity and Specificity" filed January 13, 2001 and February 23, 2001 these applications herein incorporated by reference in their entirety." Applicants' are

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required to indicate all of the appropriate U.S. Provisional Applications to which the instant application claims benefit of.

**Appropriate Correction Is Required.**

**No Claims Are Allowed.**

*EXAMINER INFORMATION*

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:

*January 27, 2003*  
*CSM*

*Marianne P. Allen*  
MARIANNE P. ALLEN  
PRIMARY EXAMINER

~~GROUP 1806~~  
*AC1631*